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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,506	01/28/2004	Michael J. Welsh	P04385US02	3490
22885	7590	06/16/2005	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309-2721			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/766,506

Applicant(s)

WELSH ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-10 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

***Detailed Action***

The following is responsive to applicant's response and terminal disclaimer received Jan. 24, 2005.

No claims are cancelled. No new claims are added. Claims 1-10 are currently pending.

The previous claim rejection under 35 USC 112, first paragraph set forth on pages 2-4 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's response and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) over Uhari et al., 5,719,196 set forth on page 5 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's response and the remarks contained therein.

The previous obviousness-type double patenting rejection set forth in paragraph 1 (pages 7-8) of the office action mailed Sep. 22, 2004 is withdrawn in view of the terminal disclaimer received Jan. 24, 2005, which has been approved and recorded.

***Claim Rejection under 35 USC 102(b) over Franz 5,527,831:***

However, applicant's arguments traversing the previous claim rejection under 35 USC 102(b) over Franz set forth on page 5 of the office action mailed Sep. 22, 2004 have been considered but are not found to be persuasive.

Applicant argues Franz does not teach each element of claim 5 because the method disclosed in Franz treats an eye that has increased intraocular pressure of aqueous humor with a xylitol solution, rather than applicant's method, which treats an infected eye by promoting antimicrobial activity against infectious cells. Additionally,

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Franz does not teach the reduction of ionic strength with a low permeability non-ionic osmolyte for the prevention or treatment of infection by promoting antimicrobial activity against infectious cells.

Said arguments have been considered but are not found to be persuasive.

Franz discloses administering topically (i.e. externally) to the eye of an individual a composition containing xylitol. The claims remain anticipated by Franz because Franz discloses administration of an identical agent, i.e. xylitol, to a patient, using Applicant's claimed method steps. Accordingly, the resulting effect of a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

Additionally, it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the Franz reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on the method. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

Therefore, the rejection is respectfully maintained.

***Claim Rejection—35 USC 102(e) over Jones 6,054,143***

Applicant argues that the Jones reference simply provides a general disclosure of a means of cleaning the nasopharynx to reduce the population of pathogenic bacteria through nasal administration of a xylitol solution. Jones does not teach the reduction of ASL ionic strength with a low permeability non-ionic osmolyte for the prevention or treatment of infection. Further, Jones only teaches the use of the nasally administered xylitol solution for the cleaning of the nasopharynx once it has become irritated. Jones, column 2, lines 13-14.

However, the instant invention recites treatment and prevention of infectious microbial cells, such as respiratory infections, by enhancing the main antibacterial defense system through administration via aerosol or powder. In addition Jones discloses that the bacteria are not killed but rather infections are reduced. The claimed invention, on the other hand, recites killing infectious cells by exposing the infectious cells to non-ionic osmolytes thereby lowering ASL sodium chloride concentration level and increasing the activity of endogenous antimicrobials.

Said arguments have been considered but are not found to be persuasive.

With respect to applicant's argument that Jones only discloses the reduction of infections but not that the bacteria are being killed, the examiner respectfully submits that the killing of the bacteria is inherent in the disclosed method. By killing the bacteria is the method able to reduce the respiratory infections.

Furthermore, the examiner respectfully submits that each and every element of the claims is met. Jones teaches administration of an identical agent, i.e. xylitol, to a

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host using Applicant's claimed method steps. Accordingly, the resulting reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method. The ionic strength of the airway epithelium surface fluid in the patient of Jones would inherently be reduced.

Finally, it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the Jones reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on the method. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

Therefore, the rejection is respectfully maintained.

***Claim Rejection—35 USC 102(a) over WO 99/27922 ('922)***

Applicant argues WO '922 simply describes that "xylitol may thus be included in a cream, jelly, lubricant or liquid or it may preferably be applied onto the surface of a condom" to treat a yeast infection (page 7, lines 5-8). WO '922 does not teach each element of the claims because the method taught by WO '922 treats a yeast infection. On the other hand, the claimed method treats infectious microbial cells in the vagina

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using a unique method to enhance antimicrobial activity. Finally, WO '922 does not teach the reduction of ionic strength with a low permeability non-ionic osmolyte for the prevention or treatment of infection by promoting antimicrobial activity against infectious cells.

Said arguments have been considered but are not found to be persuasive.

WO '922 discloses a method of treating vaginal yeast infections by administering xylitol to a patient in need thereof. The method of WO '922 serves to kill the yeast (i.e. infectious cells) causing the infection. WO '922 continues to anticipate the claims because WO '922 discloses administration of an identical agent, i.e. xylitol, to the vagina of a patient using Applicant's claimed method steps. Accordingly, the resulting reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method. In other words, the ionic strength of the vaginal surface fluid in the patients of WO '922 would inherently be reduced and antimicrobial activity against the yeast would inherently occur.

Moreover, it is reasonable to conclude that the same patient is being administered the same composition by the same mode of administration in the same amount in both the instant claims and the WO '922 reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to received a patent on the method. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Please see Bristol-Meyers Squibb Co. v. Ben Venue Laboratories, 58 USPQ2d 1508 (CAFC 2001).

Therefore, the rejection is respectfully maintained.

***Conclusion***

Claims 1-10 stand rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.



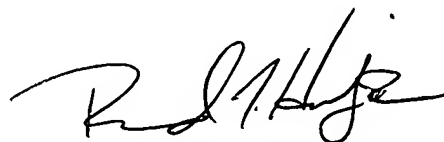
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 

June 13, 2005

  
RAYMOND HENLEY III  
PRIMARY EXAMINER  
Aul614